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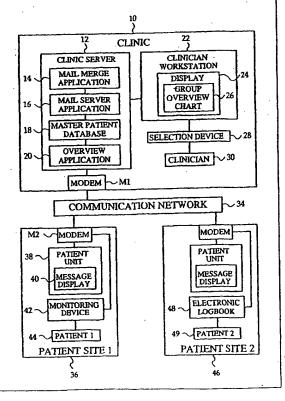
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(54) Title: MULTIPLE PATIENT MONITORING SYSTEM FOR PROACTIVE HEALTH MANAGEMENT

(57) Abstract

A system and method for monitoring a group of patients (36, 46) having a chronic disease or ongoing health condition. The method includes the step of collecting from each patient a corresponding set of measurements (44) of a control parameter of the health condition. Each set of measurements has a collection date. A control value (20) is calculated for each patient from the corresponding set of measurements. The method further includes the steps of generating and displaying a group overview chart (26) having one data point for each patient. Each data point indicates the control value calculated for the corresponding patient and a time period which has clapsed since the collection date of the patient's corresponding set of measurements. In a preferred embodiment, the method includes the additional steps of selecting (28) from the group overview chart (26) at least one of the patients represented thereon and transmitting supervisory instructions to the at least one selected patient.



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# MULTIPLE PATIENT MONITORING SYSTEM FOR PROACTIVE HEALTH MANAGEMENT

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of copending patent application 08/732,158 filed 10/16/96, which is herein incorporated by reference.

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## BACKGROUND -- FIELD OF THE INVENTION

The present invention relates generally to computer systems for managing healthcare, and in particular to a system and method for proactively monitoring a group of patients having a chronic disease or ongoing health condition.

## BACKGROUND -- DESCRIPTION OF PRIOR ART

Managing a chronic disease or ongoing health condition requires the monitoring and controlling of a physical or mental parameter of the health condition. Examples of these parameters include blood glucose in diabetes, respiratory flow in asthma, blood pressure in hypertension, cholesterol in cardiovascular disease, weight in eating disorders, T-cell or viral count in HIV, and frequency or timing of episodes in mental health disorders. Because of the continuous nature of these health conditions, their corresponding parameters must be monitored and controlled on a regular basis by the patients themselves outside of a medical clinic.

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Typically, the patients monitor and control these parameters in clinician assisted self-care or outpatient treatment programs. While these outpatient treatment programs offer significant advantages for patients and healthcare providers, they present the assisting clinician with two problems in effectively managing the medical priorities of his or her patients.

The first problem is in determining each patient's current medical status. Since the patients themselves monitor their health conditions, the clinician is often limited to learning each patient's status strictly through patient initiated events, such as an emergency visit or the delivery of the patient's latest medical data. Even with the current availability of remote monitoring devices that store and transmit medical data from a patient's home to a clinic, the clinician must still wait for medical information whose arrival depends on the patient's initiative.

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As a result, the majority of the clinician's time is spent with the patients who are the most motivated and eager for a response, while the greatest medical needs remain with the unmotivated patients who do not visit the clinician or transmit their medical data. These unmotivated patients often develop urgent medical needs that could have been prevented with proper medical management. Consequently, the cost of treating their chronic health conditions is much higher than one might expect given the sophistication of current medical monitoring devices.

The second problem is in determining which patients are having the greatest difficulty in controlling their health condition so that the clinician may focus attention on these patients. Unfortunately, most existing healthcare

information systems are only designed to display medical data on an individual patient basis. Few systems have been developed that enable clinician's to view medical data for an entire group of patients simultaneously. Consequently, it is extremely difficult for a clinician to prioritize his or her time and efforts in a manner that optimizes care and minimizes costs and complications for the entire group of patients.

Many systems have been developed for remote monitoring of a group of patients. For example , U.S. Patent 5,357,427 issued to Langen et al. on October 18, 1994 describes a system for simultaneous remote monitoring of a group of high risk patients using artificial intelligence. The system includes for each patient a remote monitoring device, such as 15 a blood pressure cuff, glucometer, etc. The remote monitoring device is connected to a telemedical interface box which transmits monitored data over a telephone line to a data recording system. Data is also collected from each patient using an artificial intelligence program that asks the patient questions through a telephone. A computer is connected to the recording system to display individual patient messages indicating a current symptom of one of the patients.

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Although Langen's system does allow simultaneous monitoring of a group of patient's, it lacks a display mechanism for simultaneously displaying summary data for the entire group of patients. Langen's system also lacks a mechanism for indicating which patients have been out of contact with the clinician and therefore have an unknown current medical status. Consequently, Langen's system is ineffective in aiding the clinician to prioritize his or her time and efforts in managing the medical priorities of an entire group of patients.

Another medical monitoring system designed to monitor a group of patients is disclosed in U.S. Patent 5,331,549 issued to Crawford on July 19, 1994. Crawford's system includes a plurality of vital signs monitors for monitoring a plurality of patients, each monitor providing continuous data to a central server. A supervisory screen is connected to the server to display a normal status or varying levels of alarm status of the vital signs of individual patients. The system permits an overview display of a hospital floor as well as a zoom in display of an individual patient site. The system further provides a warning alarm signal when any one or more vital signs of an individual patient is outside of a predetermined limit.

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While Crawford's system does allow simultaneous viewing of the vital sign status of each patient in a group, it is only directed at monitoring a group of patients who are continually connected to their vital sign monitors. Crawford's overview screen lacks any mechanism for indicating

20 Crawford's overview screen lacks any mechanism for indicating which patients have been out of contact with a clinician since continual contact is assumed.

Further, the summary data presented for each patient on the overview screen is limited to an indication of a normal state or alarm state of each patient's vital signs. Consequently, the system only allows a clinician to determine which patients are having the greatest difficulty in controlling their health condition when an actual emergency situation exists. Thus, Crawford's system is effective as a medical alarm system, but of little use to a clinician in managing the medical priorities of a group of patients who are not continually monitored in a healthcare facility.

## OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a multiple patient monitoring system that allows a clinician to view and manage the medical priorities of an entire group of patients having a chronic health condition. It is another object of the invention to provide a multiple patient monitoring system that allows a clinician to communicate proactively with unmotivated patients who have lost contact with the clinician. A further object of the invention is to provide a multiple patient monitoring system that allows a clinician to optimize efforts and minimize costs in managing the medical needs of the entire group of patients.

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These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY OF THE INVENTION

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The invention presents a system and method for monitoring a group of patients having a chronic disease or ongoing health condition. The method includes the step of collecting from each patient a corresponding set of measurements of a control parameter of the health condition. Each set of measurements has a corresponding collection date. For each patient, a control value is calculated from the corresponding set of measurements, the control value indicating the patient's control over the health condition. In the preferred embodiment, the control value calculated for each patient comprises a mean value of the patient's corresponding set of measurements.

The method also includes the step of determining for each patient a time period which has elapsed since the collection date of the patient's corresponding set of measurements. The method further includes the steps of generating and displaying a group overview chart having a plurality of data points. Each of the data points on the chart represents one corresponding patient and indicates the control value and the time period determined for the corresponding patient.

In the preferred embodiment, the method includes the additional steps of selecting from the group overview chart at least one of the patients represented thereon and transmitting supervisory instructions to the at least one selected patient. In one embodiment, the supervisory instructions are transmitted in an electronic mail message. In another embodiment, the supervisory instructions are transmitted in an automated telephone message.

A preferred system for implementing the method of the
invention includes a plurality of recording devices, such as
remote monitoring devices or electronic logbooks, for
recording the corresponding set of measurements for each
patient. The system also includes a master patient database
for receiving and storing each set with a corresponding
collection date. A communication network connects the
recording devices to the master patient database and
transmits the recorded sets of measurements therebetween.

A processor is connected to the database for determining for each of the patients the control value and time period elapsed since the collection date of the patient's corresponding set of measurements. The processor further includes a chart generation application for generating the group overview chart. A display is connected to the processor for displaying the group overview chart.

In the preferred embodiment, a selection device, such as a mouse or keyboard, is connected to the processor for selecting from the group overview chart at least one of the patients represented thereon. In this embodiment, the processor further includes an automated response application for transmitting supervisory instructions to the at least one selected patient. In one embodiment, the automated response application comprises a mail merge application for generating and transmitting the supervisory instructions in an electronic mail message. In another embodiment, the automated response application comprises an automated telephone call processing application for transmitting the supervisory instructions in a telephone message.

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## BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a schematic block diagram of a multiple patient monitoring system according to the invention.
  - FIG. 2 is a schematic block diagram illustrating the collecting of data from each patient according to the invention.
- FIG. 3 is a sample group overview chart according to the invention.
  - FIGS. 4-5 are sample electronic mail messages containing supervisory instructions for a patient.
  - FIG. 6 is a flow chart illustrating steps included in the method of the invention.
- 30 FIG. 7 is a schematic block diagram of another multiple patient monitoring system according to the invention.
  - FIG. 8 is a sample telephone message containing supervisory instructions for a patient.

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#### DESCRIPTION

A preferred embodiment of the invention is illustrated in FIGS. 1 - 6. FIG. 1 shows the main components of a system for monitoring a group of patients having an ongoing health condition. A healthcare clinic 10 has a clinic server computer 12 that includes a mail merge application 14, a mail server application 16, a master patient database 18, and a patient overview application 20. Mail merge application 14 is designed to generate electronic mail messages containing supervisory instructions to selected patients in the group, as will be explained in the operation section below. Mail server application 16 is a conventional electronic mail server designed to transmit the generated electronic mail messages to the selected patients.

Master patient database 18 is for storing patient data relating to each patient managed by clinic 10. Overview application 20 is a controlling software application for performing various calculations using the patient data stored in master patient database 18 and for generating a group overview chart with the patient data, as will be explained in detail below. Clinic server 12 is coupled to a modem M1 for connecting server 12 to a communication network 34, preferably a public telephone network or similar data transmission network.

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A clinician workstation 22 is networked to clinic server 12. Clinician workstation 22 is preferably a personal computer or network terminal. Workstation 22 has a display 24 for displaying to a clinician 30 a group overview chart 26. Workstation 22 further includes a user selection device 28, such as a mouse or keyboard, for selecting patients represented on group overview chart 26 to receive supervisory instructions from clinician 30.

A patient unit 38 for receiving electronic mail messages from mail server 16 is located at a first patient site 36, typically the patient's home. Patient unit 38 includes a message display 40 for displaying the electronic mail messages. In the preferred embodiment, patient unit 38 is a personal computer having a display monitor. However, in alternative embodiments, patient unit 38 may be any information processing and display unit,—such as a network terminal, a television set with a set—top cable converter box, a personal digital assistant, or a video game system. Patient unit 38 is connected to a modem M2 such that patient unit 38 is networked to communication network 34.

A recording device, such as a remote monitoring device 42, is also connected to modem M2. Device 42 is for collecting from a first patient 44 a corresponding set of measurements of a control parameter of the patient's health condition, such as blood glucose levels for a diabetic patient, peak flow rates for an asthmatic patient, or blood pressure for a hypertension patient. Device 42 is capable of recording each measurement in the set with a corresponding measurement date and measurement time. Device 42 is designed to record the set of measurements and transmit the recorded set to database 18 through communication network 34. Such monitoring devices for recording and transmitting measurements of a parameter of a health condition are well known in the art.

A second patient site 46 includes the same equipment as first patient site 36, with the exception of the recording device used by a second patient 49. The recording device at second patient site 46 is an electronic logbook 48 for recording a corresponding set of measurements entered in logbook 48 by second patient 49. Logbook 48 is capable of recording each measurement in the set with a corresponding measurement date

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and measurement time. Logbook 48 is designed to transmit the set of measurements recorded therein to database 18 through communication network 34. Such electronic logbooks for recording and transmitting data are well known in the art. The use of logbook 48 to record and transmit patient data enables those patients with mental health conditions or other condition whose control parameters may not be physically measured to participate in the patient monitoring system.

10 For simplicity of illustration, only two patient sites and two corresponding patients are shown in FIG. 1. It is obvious that the system of the invention may be effectively used to monitor a great number of patients. In a typical implementation, hundreds of patient sites are connected to clinic server 12 via communication network 34.

FIG. 2 is a schematic block diagram illustrating the data which is collected from each patient and stored in master patient database 18. The data collected from each patient includes at least one corresponding set of measurements 50 of the control parameter of the health condition. Each set of measurements 50 includes at least one measurement 52. Each measurement 52 includes a measured control parameter value 54, such as a blood glucose level for a diabetic patient, a peak flow rate for an asthmatic patient, or a blood pressure reading for a hypertension patient. Each measurement 52 further includes a measurement date 56 and a measurement time 58.

The actual number of measurements in each set varies in dependence upon the nature of the health condition being monitored and the duration of time over which the measurements are recorded. For example, diabetic patients typically measure their blood glucose levels several times per day, so that these patients preferably record 20 to 40

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measurements in a typical week of monitoring. However, hypertension patients may only be required to measure their blood pressure once a week, so that these patients would record only one measurement in a typical week of monitoring.

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Each set of measurements 50 is transmitted to database 18.

Database 18 stores patient records 60 for each patient participating in the monitoring system. Each patient's records include patient information 62 comprising a patient name, a patient telephone number, and a patient electronic mail address. Each patient's records also include each corresponding set of measurements 50 received from the patient. Each set 50 has a corresponding collection date 64.

15 In the preferred embodiment, collection date 64 is the date the corresponding set of measurements are received by clinic server 12. In an alternative embodiment, collection date 64 is the date the corresponding set of measurements are transmitted to the clinic. In another embodiment, collection date 64 is the measurement date 56 of a most recent measurement in the corresponding set of measurements.

Overview application 20 is designed to perform various calculations and comparisons using the patient data stored in database 18. First, overview application 20 is designed to calculate a control value for each patient from the patient's at least one corresponding set of measurements. Each control value indicates the corresponding patient's control over the health condition. In the preferred embodiment, the control value calculated for each patient is a mean value of the control parameter values recorded by the patient over a preselected period of time. In an alternative embodiment, the control value calculated for each patient is a mean value of the control value calculated for each patient is a mean value of the control parameter values in a set of measurements most recently collected from the patient.

The preselected period of time used to calculate the control value varies in dependence upon the nature of the patient's health condition. For example, a useful period of time for calculating a mean blood glucose value for diabetes patients is typically one week, while a useful period of time for calculating a mean daily number of panic attacks for phobic patients is typically two weeks. The actual period of time used to calculate the control value is preselected and programmed in overview application 20 according to guidelines prescribed by the clinician.

Second, overview application 20 is designed to determine for each patient a time period which has elapsed since the collection date of the set of measurements most recently collected from the patient. For example, if a patient has only transmitted to the clinic one set of measurements, overview application 20 determines the time that has elapsed since the collection date of the one set. If a patient has transmitted to the clinic multiple sets of measurements, overview application 20 determines the time that has elapsed since the most recent collection date.

Third, overview application 20 is designed to determine the compliance of each patient with a clinician prescribed measurement regimen. The prescribed measurement regimen preferably includes prescribed measurement dates and prescribed measurement times. To determine the compliance of each patient, overview application 20 compares each patient's actual measurement dates and times with the prescribed measurement dates and times.

For example, it is usually important that a diabetic patient measure his or her fasting blood glucose level every morning before breakfast. Thus one prescribed measurement time for a

diabetes patient is 7 am, or similar pre-breakfast time.

Overview application 20 compares the diabetes patient's actual measurement times with the prescribed pre-breakfast time to ensure that the patient is complying with the measurement regimen. Of course, many other prescribed measurement regimens are possible and are selected according to guidelines provided by the clinician.

In the preferred embodiment, the prescribed measurement regimen also includes a prescribed number of measurements to be taken by the patient over a prescribed time period.

Overview application 20 is further capable of determining a completeness of each set of measurements relative to the prescribed measurement regimen.

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Continuing with the example of the diabetic patient, a typical prescribed measurement regimen requires 3 measurements of the patient's blood glucose level per day. In this example, overview application 20 compares the actual number of measurements recorded by the patient on each measurement date to the three prescribed measurements per day to determine the completeness of the set. Specific techniques for writing and implementing an overview application that performs the calculations and comparisons described above are well known in the art.

Overview application 20 is further capable of generating group overview chart 26. FIG. 3. illustrates a sample group overview chart generated for a group of ten diabetes patients. Chart 26 has ten data points, each data point representing one corresponding patient and indicating the control value calculated for the patient and the time period elapsed since the patient's most recent collection date. In the preferred embodiment, each data point is represented on chart 26 by a corresponding icon 66.

Each icon 66 indicates the compliance of the corresponding patient with the prescribed measurement regimen. A chart key 68 is provided on chart 26 to explain the significance of each icon's appearance. Non-compliant patients are represented by flashing icons, while compliant patients are represented by non-flashing icons. In FIG. 3, the flashing icons having dotted borders, while the non-flashing icons have solid borders. In an alternative embodiment, non-compliant patients are represented by icons having a first color, while compliant patients are represented by icons having a second color.

Each icon 66 further indicates the completeness of the set of measurements most recently collected from the corresponding patient. Patients having complete sets are represented by filled icons, while patients having sparse sets are represented by blank icons. Of course, in alternative embodiments, the appearance of each icon 66 may be varied in alternative ways to indicate the compliance of the corresponding patient and the completeness of the corresponding patient's measurements.

Chart 26 further includes a list box 70, a print list button 74, and a send message button 76. List box 70 is for displaying a list of names of the patients selected from chart 26 by the clinician. The icons corresponding to the selected patients are highlighted, as represented by dotted circles 72. Print list button 74 is for sending the list of names to a printer (not shown) to obtain a print out of the list. Send message button 76 is for transmitting the list to mail merge application 14.

Referring to FIG. 4, mail merge application 14 is designed to generate for each selected patient a corresponding electronic

mail message 78. Each message 78 contains supervisory instructions for the corresponding patient. Mail merge application 14 is capable of customizing each message 78 to include for the corresponding patient, the patient's name, the patient's electronic mail address, and the collection date of the patient's most recent set of measurements. The programming of a mail merge application to generate customized messages in this manner is well known in the art. FIG. 5 illustrates an alternative message 80 containing different instructions for each patient. Of course, messages containing many other instructions are possible in alternative embodiments.

The operation of the preferred embodiment is illustrated in FIG. 6. FIG. 6 is a flow chart showing a preferred method of 15 using the system to monitor a group of patients having a health condition. Each patient is provided with a corresponding recording device, such as remote monitoring device 42 or electronic logbook 48. In step 200, each 20 patient records in his or her recording device at least one corresponding set of measurements 50 of a control parameter of the health condition. In step 202, the recorded sets of measurements are transmitted from each recording device to database 18 through network 34. Each set of measurements is stored in database 18 with its corresponding collection date 25 64, step 204.

In step 206, overview application 20 calculates for each patient a control value from the patient's corresponding set of measurements. Next, application 20 determines the compliance of each patient with the prescribed measurement regimen by comparing the actual measurement times of the patient's corresponding measurements to the prescribed measurement times in the measurement regimen, step 208.

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In step 210, application 20 determines for each patient the completeness relative to the prescribed measurement regimen of the corresponding set of measurements most recently collected from the patient. Application 20 then determines for each patient the time period which has elapsed since the corresponding collection date 64 of the set of measurements most recently collected from the patient, step 212.

Next application 20 generates group overview chart 26, step 214. In step 216, chart 26 is displayed on display 24, as shown in FIG. 3. Each data point on chart 26 is displayed as a corresponding icon 66. Each data point represents one corresponding patient and indicates the control value and the elapsed time period determined for the corresponding patient.

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Each icon 66 indicates the compliance of the corresponding patient with the prescribed measurement regimen. Each icon 66 further indicates the completeness of the corresponding set of measurements most recently collected from the corresponding patient. Thus chart 26 allows clinician 30 to easily determine which patients in the group have been out of contact with clinic 10, which patients are having the greatest difficulty in controlling the health condition, and which patients are having difficulty complying with the prescribed treatment plan.

Next, clinician 30 uses selection device 28 to select from chart 26 at least one of the patients represented thereon, step 218. Typically, selection device 28 is a mouse or similar pointing device, and clinician 30 selects patients from chart 26 by clicking the icon corresponding to the patient. As clinician 30 selects each patient, list box 78 displays the name of each selected patient. Next clinician 30 selects send message button 76 to transmit the list of selected patients to mail merge application 14.

Application 14 generates for each selected patient corresponding electronic mail message 78. Each message 78 contains supervisory instructions for the corresponding patient. Mail merge application 14 customizes each message 78 to include for the corresponding patient, the patient's name, the patient's electronic mail address, and the collection date of the patient's most recent set of measurements. In step 220, mail server—application 16 transmits each message 78 through network 34 to the corresponding patient. When the patients receive the supervisory instructions, they continue the monitoring loop with clinician 30, step 226, by returning to step 200 and repeating the method described.

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The advantage of the multiple patient monitoring system of the preferred embodiment is that it allows the clinician to view and manage the medical priorities of an entire group of patients simultaneously. It also allows the clinician to communicate proactively with unmotivated patients who have lost contact with the clinician before these patients develop urgent medical needs. Consequently, the system allows the clinician to optimize efforts and minimize costs in managing the care of the entire group of patients.

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A second embodiment of the invention is shown in FIGS. 7 - 8. The second embodiment differs from the preferred embodiment in the method of transmitting supervisory instructions to each patient selected from chart 26. Referring to FIG. 7, clinic server 12 includes an automated telephone call processing application 82 in place of mail merge application 14 and mail server application 16. Call processing application 82 is designed to generate for each selected patient a corresponding automated telephone message 88, as

shown in FIG. 8. Each message 88 contains supervisory instructions for the corresponding patient.

Application 82 is capable of customizing each message 88 to include for the corresponding patient the patient's name and the collection date of the patient's most recent set of measurements. The programming of an automated call processing application to generate customized messages in this manner is well known in the art. Referring again to FIG. 7, clinic server 12 is connected to a telephone network 84 through a digital/tone signal converter D1. Each patient is provided with a dual tone multi-frequency telephone 86. Each telephone 86 is connected to telephone network 84 to receive automated telephone messages from clinic server 12.

The operation of the second embodiment differs from the operation of the preferred embodiment in that supervisory instructions are transmitted to the selected patients in automated telephone messages rather than in electronic mail messages. Otherwise, the operation and advantages of the second embodiment are identical to those of the preferred embodiment described above.

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#### SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of the presently preferred embodiment. Many other embodiments of the invention are possible. For example, in one alternative embodiment, each software application located on the clinic server is loaded onto the clinician workstation, and the clinic server is eliminated from the system. The clinic server is presently preferred for performing resource

intensive operations, such as storing large amounts of patient data, but the clinic server is not necessary to enable the system and method of the invention. In embodiments that include the clinic server, the clinic server need not be physically located at the clinic. The server may be located off-site and networked to the clinician computer.

Additionally, the preferred embodiment describes the use of remote monitoring devices and electronic logbooks for collecting data from each patient. However, many other methods of collecting data from patients are possible in alternative embodiments. For example, the patients could be provided with a paper based logbook and an automated reader for digitizing and transmitting the logbook information to the patient database. Alternatively, each patient could mail or fax the logbook information to the clinic for entry into the patient database. In another embodiment, the patients use DTMF telephones to connect to the patient database and enter their data through the telephone keypads.

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Further, the electronic mail messages and automated telephone message illustrated are exemplary of just one possible embodiment of the invention. Many other messages may be generated and transmitted to patients in alternative embodiments. Additionally, the preferred embodiment describes a system and method for monitoring patients having diabetes. However, the invention is not limited to monitoring diabetic patients. The system and method described are equally effective for monitoring patients having asthma, hypertension, cardiovascular disease, eating disorders, HIV, mental health disorders, or any other health condition having a measurable control parameter.

Therefore, the scope of the invention should be determined not by the examples given but by the appended claims and their legal equivalents.

#### CLAIMS

#### I claim:

A method for monitoring a group of patients having a health condition, said method comprising the following steps:
 a) collecting from each of said patients a corresponding set of measurements of a control parameter of the health condition, each said set having a corresponding

collection date:

- b) for each of said patients, calculating from the corresponding set of measurements a control value indicative of the patient's control over the health condition:
- c) determining for each of said patients a time period
  which has elapsed since the corresponding collection
  date of the corresponding set of measurements; and
  - d) generating and displaying a group overview chart having a plurality of data points, wherein each of said data points represents one corresponding patient and indicates the control value and the time period determined for the corresponding patient.

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- 2. The method of claim 1, further comprising the steps of:
  - a) selecting from said group overview chart at least one of the patients represented thereon; and
  - transmitting supervisory instructions to the at least one selected patient.

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 The method of claim 2, wherein said supervisory instructions are transmitted in an electronic mail message.

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 The method of claim 2, wherein said supervisory instructions are transmitted in a telephone message.

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5. The method of claim 1, further comprising the steps of determining a compliance of each of said patients with a prescribed measurement regimen and indicating the compliance of each of said patients on said group overview chart.

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6. The method of claim 5, wherein each of said data points is displayed on said group overview chart as a corresponding icon, and wherein each said icon indicates the compliance of the corresponding patient with said prescribed measurement regimen.

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7. The method of claim 1, further comprising the steps of determining for each of said patients a completeness of the corresponding set of measurements, the completeness being determined relative to a prescribed measurement regimen, and indicating on said chart the completeness of the corresponding set of measurements.

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8. The method of claim 7, wherein each of said data points is displayed on said group overview chart as a corresponding icon, and wherein each said icon indicates the completeness of the corresponding set of measurements collected from the corresponding patient.

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9. The method of claim 1, wherein the step of collecting from each of said patients the corresponding set of measurements comprises the steps of:

4	a) providing each of said patients with a recording
5	device for recording the corresponding set of
. 6	measurements;
7	b) transmitting the recorded sets of measurements
8	from each said recording device to a master
9	patient database; and
10	c) storing the transmitted sets of measurements in
11	said master patient database.
12	
. 1	10. The method of claim 9, wherein at least one of
2	said recording device comprises a remote
3	monitoring device.
4	
. 1	11. The method of claim 9, wherein at least one of
2	said recording device comprises an electronic
3	logbook.
4	
1	12. The method of claim 1, wherein the control value
2	calculated for each of said patients comprises a me
3	value of the corresponding set of measurements.
4	
1	13. A system for monitoring a group of patients having a
2	health condition, said system comprising:
3	a) a collection means for collecting from each of said
4	patients a corresponding set of measurements of a
5	control parameter of the health condition, each said
6	set having a corresponding collection date;
7	b) a processor means connected to said collection means
8	for determining for each of said patients:
9	<ul> <li>i) a control value calculated from the corresponding</li> </ul>
10	set of measurements, the control value indicating
11	the patient's control over the health condition;
12	and

ii) a time period which has elapsed since the 13 14 corresponding collection date of the corresponding set of measurements collected from the patient; 15 said processor means further including a chart 16 generation means for generating a group overview chart 17 having a plurality of data points, wherein each of 18 said data points represents one corresponding patient 19 and indicates the control value and the time period 20 determined for the corresponding patient; and 21 a display means connected to said processor means for 22 displaying said group overview chart. 23 24 14. The system of claim 13, further comprising a selection 1 means connected to said processor means for selecting 2 from said group overview chart at least one of the 3 patients represented thereon, and wherein said 4 processor means further includes an automated response 5 means for transmitting supervisory instructions to the 6 at least one selected patient. 7 15. The system of claim 14, wherein said automated 2 response means comprises an electronic mail means for transmitting said supervisory instructions in 3 an electronic mail message. К 16. The system of claim 14, wherein said automated response means comprises a telephone call processing means for transmitting said supervisory instructions in a telephone message. 17. The system of claim 13, wherein said processor means 1 further includes means for determining a compliance of 2

each of said patients with a prescribed measurement regimen and wherein said group overview chart includes

means for indicating the compliance of each of said patients with said prescribed measurement regimen.

18. The system of claim 17, wherein said means for indicating the compliance of each of said patients comprises a plurality of icons displayed on said chart, each of said icons corresponding to one of said data points and indicating the compliance of the one corresponding patient represented by the corresponding data point.

19. The system of claim 13, wherein said processor means further includes means for determining for each of said patients a completeness of the corresponding set of measurements, the completeness being determined relative to a prescribed measurement regimen, and wherein said group overview chart includes means for indicating the completeness of the corresponding set of measurements collected from each said patient.

20. The system of claim 19, wherein said means for indicating the completeness of the corresponding set of measurements collected from each said patient comprises a plurality of icons displayed on said chart, each of said icons corresponding to one of said data points and indicating the completeness of the corresponding set of measurements collected from the one corresponding patient represented by the corresponding data point.

21. The system of claim 13, wherein said collection means comprises:

3		a) a plurality of recording devices, each said
4		recording device recording the corresponding set
5		of measurements for at least one of said patients;
6		b) a master patient database for storing each said
. 7		set of measurements recorded in said recording
8		devices; and
9		c) a communication network for transmitting each said
10		set of measurements from said recording devices to
11		said master patient database.
12		
1		22. The system of claim 21, wherein at least one of
2		said recording devices comprises a remote
3		monitoring device.
4		
1		23. The system of claim 21, wherein at least one of
2		said recording devices comprises an electronic
3		logbook.
4		
1	24.	The system of claim 13, wherein the control value
2	•	calculated for each said patient comprises a mean
3		value of the corresponding set of measurements
4		collected from the patient.
5		
1	25. A m	ethod for monitoring a group of patients having a
2	hea	lth condition, said method comprising the following
3	ste	ps:
4	a)	collecting from each of said patients at least one
5		corresponding set of measurements of a control
6	•	parameter of the health condition, each said set
7		having a corresponding collection date;
8	b)	for each of said patients, calculating from the at
, <b>9</b> ,	•	least one corresponding set of measurements a control
10.		value indicative of the patient's control over the
11		health condition;

determining for each of said patients a time period 12 which has elapsed since the corresponding collection 13 date of a set of measurements most recently collected 14 from the patient; and 15 generating and displaying a group overview chart 16 having a plurality of data points, wherein each of 17 said data points represents one corresponding patient 18 and indicates the control value and the time period 19 determined for the corresponding patient; 20 selecting from said group overview chart at least one 21 of the patients represented thereon; and 22 transmitting supervisory instructions to the at least 23 one selected patient. 24 25 26. The method of claim 25, wherein said supervisory 1 instructions are transmitted in an electronic mail message. 3 27. The method of claim 25, wherein said supervisory 1 instructions are transmitted in a telephone message. 2 28. The method of claim 25, further comprising the steps 1 of determining a compliance of each of said patients 2 with a prescribed measurement regimen and displaying each of said data points on said group overview chart as a corresponding icon, wherein each said icon indicates the compliance of the corresponding patient with said prescribed measurement regimen. 8 29. The method of claim 25, further comprising the steps 1 of determining for each of said patients a 2 completeness of the corresponding set of measurements 3 most recently collected from the patient, the completeness being determined relative to a prescribed

	measurement regimen, and displaying each of said data
6	measurement regimen, and displaying second as a corresponding
7	points on said group overview chart as a corresponding
8	icon, wherein each said icon indicates the
9	completeness of the corresponding set of measurements
10	most recently collected from the corresponding
11	patient.
12	the star of gollogting
1	30. The method of claim 25, wherein the step of collecting
2	from each of said patients the at-least one
3	corresponding set of measurements comprises the steps
4	of:
5	a) providing each of said patients with a recording
6	device for recording the at least one
7	corresponding set of measurements;
8	b) transmitting the recorded sets of measurements
9	from each said recording device to a master
10	patient database; and
11	c) storing the transmitted sets of measurements in
12	said master patient database.
13	
1	31. The method of claim 30, wherein each said
2	recording device comprises a remote monitoring
3	device.
4	
1	32. The method of claim 30, wherein each said
2	recording device comprises an electronic logbook.
- 3	
1	33. The method of claim 27, wherein the control value
2	calculated for each said patient comprises a mean
. 3	value of the at least one corresponding set of
4	measurements collected from the patient.

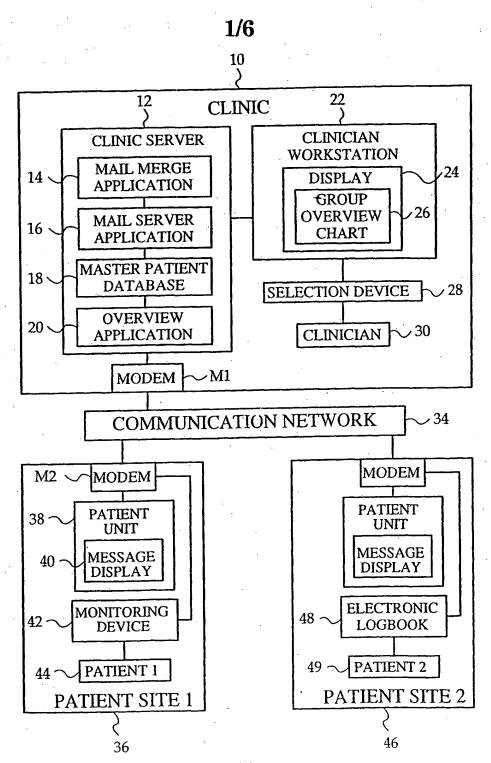


FIG. 1

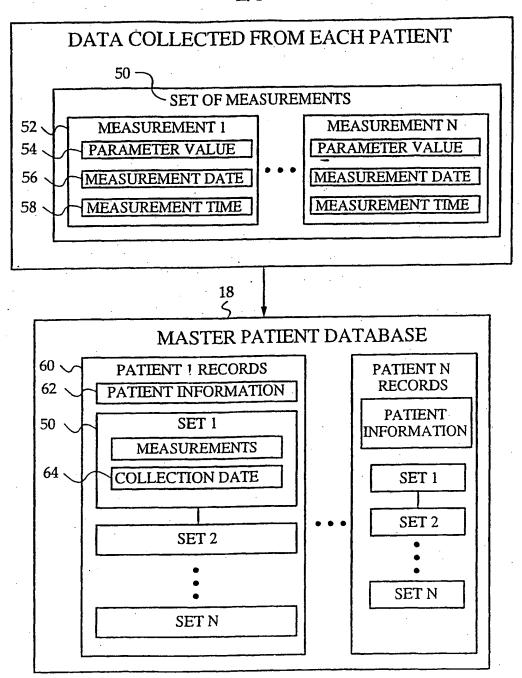
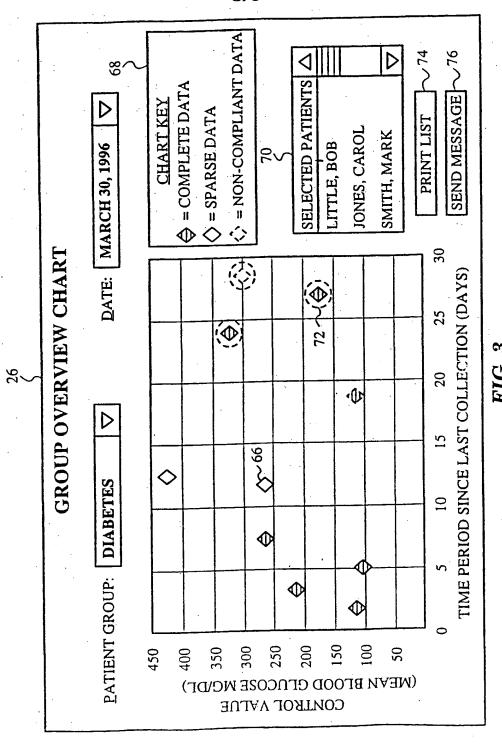


FIG. 2



4/6

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TO:

<< INSERT PATIENT MAIL ADDRESS >>

SUBJECT:

REQUEST FOR BLOOD GLUCOSE MEASUREMENTS

# Hello << INSERT PATIENT NAME >>,-

I have not received your blood glucose measurements since << INSERT COLLECTION DATE >> and I am concerned that your blood glucose level stay in control. Please transmit your latest measurements to the clinic today.

Sincerely,

Dr. Peters

FIG. 4

80

TO:

<< INSERT PATIENT MAIL ADDRESS >>

SUBJECT:

MEASURE YOUR BLOOD GLUCOSE REGULARLY

# Hello << INSERT PATIENT NAME >>,

Your last set of blood glucose measurements did not include an adequate number of measurements to assess your progress in controlling diabetes. Please remember to test your blood glucose regularly so that we may work together to keep your diabetes in control.

Sincerely,

Dr. Peters

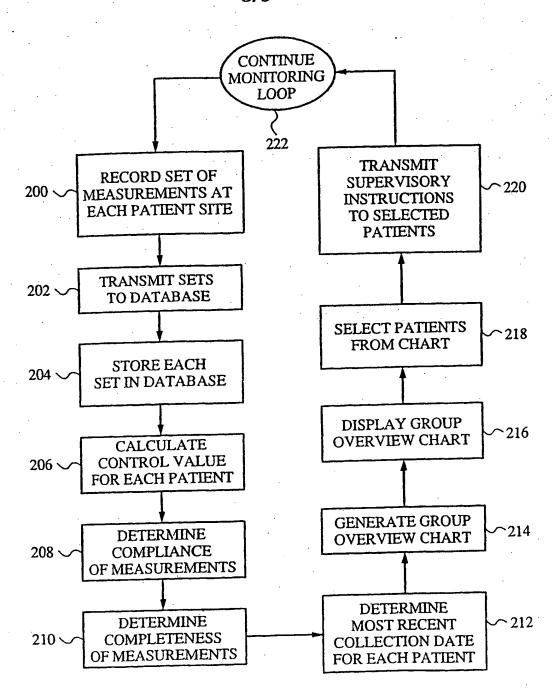
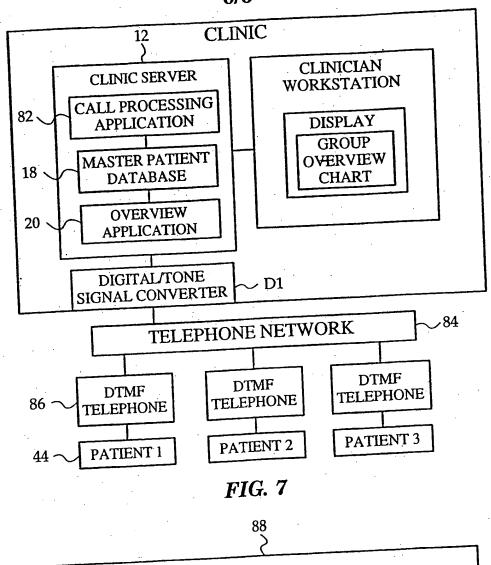


FIG. 6





This is Dr. Peters calling from the Medical Clinic for << INSERT PATIENT NAME >>. If this is <<INSERT PATIENT NAME>>, press 1.

I have not received your blood glucose measurements since << INSERT COLLECTION DATE >> and I am concerned that your blood glucose level stay in control. Please transmit your latest measurements to the clinic today.

# INTERNATIONAL SEARCH REPORT

Int Ional Application No PCT/US 99/21052

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DOCUME	NTS CONSIDERED TO BE RELEVANT		Relevant to claim No
ategory *	Citation of document, with indication, where appropriate, of the re	elevant passages	Melekara to oldan
, alogory		·	1 22
	WO 98 16895 A (RAYA SYSTEMS, INC	:) ·	1-33
Χ.	22 April 1008 (1998-04-23)		
	page 6, line 13 -page 16, line 3	3; tables	
	1-8	-	·
	EP 0 680 727 A (BOEHRINGER MANNI	HETM GMBH)	1-4,9,
1	8 November 1995 (1995-11-08)		10,
	8 Movelines 1333 (1332 11 c-)	•	13-16, 21,22,
	·		25-27,
			30,31
	11 15	no 46:	
	column 7, line 1 -column 11, li	He 40,	-
	tables 1-3		
		-/	
			led in appeal
X Fu	orther documents are listed in the continuation of box C	Patent tamily members are lis	
* Special	categories of cited documents:	"T" later document published after the or priority date and not in conflict.	international filing date with the application but
TAR door	most defining the general state of the lart which is not	cited to understand the principle of	r theory underlying the
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	ment which may throw doubts on priority claim(s) or the size of the publication date of another this cited to establish the publication date of another	"Y" document of particular relevance; t	he claimed invention
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### INTERNATIONAL SEARCH REPORT

In' Jonal Application No PCT/US 99/21052

		PC1/03 99/21032	
/Continue	tion) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to	claim No
ategory •	Citation of document, with indication, where appropriate, of the relevant passages	·	
1	EP 0 761 160 A (AKASAKA, NOBORU ET AL) 12 March 1997 (1997-03-12)	10 13 21 25	1,9, -16, ,22, -27, ,31
	column 2, line 40 -column 5, line 53; tables 1,2	1-	4,
A	WO 96 25877 A (BRIGHAM AND WOMENS HOSPITAL) 29 August 1996 (1996-08-29)	13	-16, 5-27
	page 2, line 11 -page 4, line 15 page 9, line 19 -page 12, line 4; table 1		
A	EP 0 526 166 A (DESSERTINE, ALBERT L.) 3 February 1993 (1993-02-03) column 6, line 30 - line 58; table 3		,7,17, 9,28
		·	
ľ			

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inc. donal Application No PCT/US 99/21052

Patent document	Publication date		Patent family member(s)		Publication date
cited in search report WO 9816895	<u>_</u>	23-04-1998	US AU	5832448 A 4979197 A	03-11-1998 11-05-1998
EP 0680727	A	08-11-1995	DE AU CA CN FI HU IL JP NO NZ US ZA	4415896 A 674474 B 1763495 A 2148569 A 1128353 A 952131 A 75243 A 113569 A 7311196 A 951754 A 272000 A 5507288 A 9503585 A	09-11-1995 19-12-1996 07-12-1995 06-11-1995 07-08-1996 06-11-1995 28-05-1997 04-01-1998 28-11-1995 06-11-1995 24-04-1997 16-04-1996 04-11-1996
EP 0761160	Α	12-03-1997	JP US	9047436 A 5785650 A	18-02-1997 28-07-1998
WO 9625877	Α	29-08-1996	US AU	5778882 A 5356996 A	14-07-1998 11-09-1996
EP 0526166	Α	03-02-1993	NON	IE	

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